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Subject: INSIDE EPA- 3/18/11- IRIS- Formaldehyde -NTP

FYI

Inside EPA - 03/18/2011

NTP Expected To List Formaldehyde As Carcinogen, Bolstering EPA

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Health and Human Services Secretary Kathleen Sebelius is poised to release the National Toxicology Program's (NTP) 12th report on chemicals the agency deems carcinogenic to humans, and is expected to list formaldehyde for the first time – a move that could further solidify EPA's stance that the chemical is a carcinogen just as a National Academy of Sciences (NAS) panel moves closer to unveiling its review of the agency's draft risk assessment.

Congress first ordered NTP to produce the Report on Carcinogens (RoC) in 1978, according to the program's website. The documents provide information on chemicals that NTP deems carcinogenic or reasonably anticipates to be human carcinogens, along with people's potential for exposure to them, whether they are genotoxic and how they cause cancer.

NTP Director Linda Birnbaum said during remarks at the Society of Toxicology annual meeting in Washington, DC, March 10 that Sebelius could release the 12th RoC as early as this month.

"We are supposed to release the RoC every two years. The last one was released in 2005; there was a lot of back and forth with the [White House Office of Management and Budget]," Birnbaum said. "They finally approved our new [RoC] review process in 2008."

NTP's 12th RoC has long been expected to list formaldehyde as a carcinogen. An expert panel reviewing NTP's background document on formaldehyde unanimously voted the chemical -- both naturally produced and widely used in industry -- a human carcinogen after considering a controversial study of Chinese workers published in early 2010 that indicated that exposure to formaldehyde caused certain types of leukemia.

EPA researchers considered the same study when writing their June 2010 draft Integrated Risk Information System (IRIS) assessment of formaldehyde, as did the International Agency for Research on Cancer when it voted formaldehyde a human carcinogen in late 2009. EPA's draft IRIS assessment of formaldehyde is undergoing review by the NAS, under an agreement that Administrator Lisa Jackson struck with Sen. David Vitter (R-LA) in 2009. Vitter placed a hold on the nomination of EPA research chief until Jackson agreed to fund an NAS review of the formaldehyde assessment.

NAS' report is also expected to be released this month, according to the NAS website.

Release of the NTP report and the NAS review of EPA's draft assessment comes amid growing disputes over the chemical's risks and EPA regulation.

EPA in its latest national-scale air toxics assessment based on 2005 data finds that cancer risks from hazardous air pollutants (HAPs) have grown from 36 in a million to 50 in a million and that formaldehyde is now the biggest "driver" of overall air toxic cancer risks, despite what the agency says is an overall reduction in HAP levels (*see related story*).

But the chemical industry is resisting EPA efforts to strictly regulate the chemical. For example, industry officials last month urged EPA to stall a proposed air toxics rule for wood furniture manufacturing facilities until the NAS completes its review, saying the 1991 risk assessment that EPA was relying on is "overly conservative."

NTP's new process for drafting the RoC documents includes requesting nominations from the public for chemicals to be added to the listing, or re-examined. NTP staff then select those studies to potentially include, and drafts a background document relating each substance's carcinogenic potential. Each of these documents is reviewed by an external panel of experts, who recommend whether and how to list the substance in the RoC. NTP updates the background documents, which are then sent to two additional review committees for consideration before NTP presents them to its Board of Scientific Counselors for final peer review. The final draft is then reviewed by the NTP director and NTP executive committee before it is submitted to Secretary Sebelius for final review and submission to Congress.

NTP initially proposed to include eight substances in the 12th RoC, including Aristolochic Acids, Captafol, Cobalt-Tungsten Carbide Powders and Hard Metals, Glass Wool Fibers, ortho-Nitrotoluene, Riddelliine and Styrene in addition to formaldehyde. -- *Maria Hegstad*

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